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MAY 2 2 2014

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Wright Medical Technology, Inc.

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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the SALVATION. Beams and Bolts System.

(a)(1). Submitted By:

Wright Medical Technology, Inc.

1023 Cherry Road Memphis, TN 38117

Date:

March 28, 2014

Contact Person:

Leslie Fitch, PhD

Senior Regulatory Affairs Specialist

Office: (901) 867-4120 Fax: (901) 867-4190

(a)(2). Proprietary Name:

SALVATIONTM 3Di Plating System

Common Name:

Bone Plate System

Classification Name and Reference:

21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories, Class II

Device Product Code, Device Panel:

HRS, Orthopedic

(a)(3). Predicate Devices:

K061808: DARCO® RPS Plates K121651: ORTHOLOC® 3Di Recon

Midfoot Plating System

K090675, K110670: Smith and Nephew VLP Foot Plating, Screw

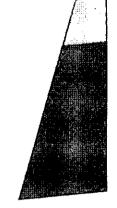
System

K131093: ORTHOLOC® 3Di Ankle

Plating System

(a)(4). Device Description

The SALVATIONTM 3Di Plating System consists of titanium alloy plates and screws used for midfoot reconstruction. The system features plates of various sizes and styles, as well as locking and non-locking screws.



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(a)(5). INTENDED USE

The SALVATIONTM 3Di Plating System is indicated for the treatment of fracture stabilization/fixation, revision procedures, osteotomies, and reconstruction/arthrodesis of small bones, as well as patients with osteopenic bone. Specific examples include: medial column fusion (talus, navicular, cuboid, first metatarsal) for neuropathic osteoarthropathy (Charcot).

(a)(6). Technological Characteristics Comparison

The SALVATION™ 3Di Plating System is technologically substantially equivalent to predicate devices in material, size and bending strength.

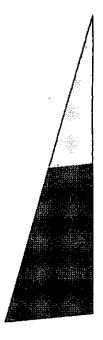
(b)(1). Substantial Equivalence – Non-Clinical Evidence

Performance testing and analysis that demonstrated substantial equivalence includes static bending, insertion, removal, and ultimate torque, as well as a pull-out rationale.

(b)(2). Substantial Equivalence – Clinical Evidence N/A

(b)(3). Substantial Equivalence - Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.





Food and Drug Administration 10903 New Hampshire Avenue Document Control Center - WO66-G609 Silver Spring, MD 20993-0002

May 22, 2014

Wright Medical Technology, Incorporated Leslie Fitch, Ph.D., CTBS Senior Regulatory Affairs Specialist 1023 Cherry Road Memphis, Tennessee 38117

Re: K140792

Trade/Device Name: SALVATIONTM 3Di Plating System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and

accessories

Regulatory Class: Class II

Product Code: HRS
Dated: April 10, 2014
Received: April 11, 2014

Dear Dr. Fitch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/McdicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson Director Division of Orthopedic Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

> Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."